Supreme Court, U.S.
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No. 10-412

IN THE

Supreme Court of the United States

VANDERBILT UNIVERSITY,

Petitioner,

v.

ICOS CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the lower courts were correct in rejecting Petitioner's request to add its scientists as co-inventors on patents under 35 U.S.C. § 256, where the district court found that Petitioner's theory regarding its scientists' alleged contribution to the inventions, when compared to the contrary account established by the patent owner, was at best only "equally plausible."

2. Whether a court of appeals may affirm a district court's judgment on an alternative ground supported by the record.

CORPORATE DISCLOSURE STATEMENT

ICOS Corporation is a wholly-owned subsidiary of Eli Lilly & Company, which is publicly traded.

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BRIEF IN OPPOSITION

INTRODUCTION

Neither of the questions presented by Petitioner Vanderbilt University merits this Court's attention. Vanderbilt lost this case not because it faced a "clear and convincing" standard of proof, but because it failed to convince the district court that its theory based on speculation was any more than "equally plausible" when compared to ICOS's contrary account based on evidence. Pet. App. 82a. There is no need for this Court to review a case where, as here, the question presented will have no effect on the outcome. Vanderbilt's petition should be denied.

1. Although the question this Court will review in *Microsoft Corp.* v. *i4i Ltd. Partnership* (No. 10-290)—the appropriate standard of proof for claims of patent invalidity over prior art references not submitted to the Patent Office—bears some resemblance to Vanderbilt's first question presented, this Court's review of *i4i* does not warrant granting or even holding Vanderbilt's petition, for at least two reasons.

First, and critically, the Federal Circuit's disposition of this case was manifestly correct *regardless* of what standard of proof is applied. As the district court found, and Vanderbilt does not deny, the record contains a complete "lack of evidence" supporting Vanderbilt's argument on several essential points. Pet. App. 79a-80a n.50. The district court accordingly held that, at the very most, Vanderbilt's speculative theory of events was "equally plausible" when compared to ICOS's contrary account based on the evidence. *Id.* 82a. That finding is dispositive, because it confirms that Vanderbilt failed to prove *even by a preponderance of the evidence* that its scientists should be added as co-inventors. Where, as here, the resolution of the question presented "is irrelevant to the ultimate outcome of the case before the Court, certiorari may be denied." Gressman *et al.*, *Supreme Court Practice* § 4.4(f), at 248 (9th ed. 2007).

Second, even were this Court to conclude in *i4i* that a preponderance-of-the-evidence standard applies to invalidity challenges based on prior art references not submitted to the Patent Office, that would not compel application of a similar standard in the correction-of-inventorship context of this case. Judicial decisions requiring clear and convincing evidence in order to correct inventorship date back decades, including prior to the 1952 enactment of the current Patent Act. Con-

gress's enactment of 35 U.S.C. § 256 did not purport to alter that common law standard, and Congress's continued failure to disturb it demonstrates legislative acquiescence. *See, e.g.*, *Merck & Co.* v. *Reynolds*, 130 S. Ct. 1784, 1795 (2010) ("We normally assume that, when Congress enacts statutes, it is aware of relevant judicial precedent."); *Watson* v. *United States*, 552 U.S. 74, 82-83 (2007) (prolonged congressional inaction following judicial construction of a statute "'enhance[s] even the usual precedential force'" accorded statutory interpretations (quoting *Shepard* v. *United States*, 544 U.S. 13, 23 (2005))). Congress's approval of the clear-and-convincing-evidence standard is confirmed by its continued refusal to revise the proof requirements in correction-of-inventorship cases. Notably, not one of the amici supporting Microsoft's petition in *i4i* has supported Vanderbilt's petition here.

2. Vanderbilt's second question presented is also unworthy of review. It is settled law that "[a] successful party in the District Court may sustain its judgment on any ground that finds support in the record." *Jaffke* v. *Dunham*, 352 U.S. 280, 281 (1957) (per curiam). Every court of appeals has applied this rule repeatedly, including in cases in which the district court has committed harmless legal error. Nothing in this Court's decision in *Pullman-Standard* v. *Swint*, 456 U.S. 273 (1982), alters that established principle of appellate review, particularly where—as here—the court of appeals affirms on a basis that the district court itself adopted as an alternative ruling.

STATEMENT

A. Dr. Daugan's Invention Of The Patented Compounds

This case turns on research conducted by Dr. Alain Daugan, a medicinal chemist at a Glaxo Wellcome Inc. research facility in Les Ulis, France. Pet. App. 33a-36a. In the early 1990s, Dr. Daugan invented certain chemical compounds that, along with compositions comprising them and methods for using them, are claimed in U.S. Patents Nos. 5,859,006 (the '006 patent) and 6,140,329 (the '329 patent), both of which were assigned to Respondent ICOS Corporation. The parties "agree that Dr. Daugan was the first to conceive" the claimed compounds. *Id.* 23a.

The specific compounds Dr. Daugan invented provide for increased relaxation of smooth muscle tissue, resulting in the widening of blood vessels (vasodilation) and increased blood flow. Pet. App. 34a. The compounds, known as "PDE5 inhibitors," inhibit the function of an enzyme called phosphodiesterase V ("PDE5"), which would otherwise break down a cyclic nucleotide called cyclic guanosine monophosphate ("cGMP"). When not broken down, cGMP activates another protein called cGMP kinase, which causes smooth muscle tissue to relax. *Id.*

The net effect of PDE5 inhibitors is smooth-muscle relaxation and increased blood flow. Pet. App. 34a. As a result, PDE5 inhibitors can be effective in treating erectile dysfunction ("ED"). *Id.* 3a. One of the compounds Dr. Daugan invented, tadalafil, became the active ingredient in Cialis®, one of the world's best-selling drugs for the treatment of ED.

Tadalafil and the other claimed compounds that Dr. Daugan invented are tetracyclic (*i.e.*, four-ringed)

molecules that comprise a particular three-ringed substructure known as a "beta-carboline." Pet. App. 59a. Dr. Daugan's invention of tadalafil resulted from a comprehensive chemical study between 1992 and 1994 that began with a "lead" compound that Glaxo designated GR30040x, which also had a beta-carboline substructure. *Id.* 60a. Dr. Richard Labaudinière, the head of chemistry and leader of Glaxo's PDE5 project in France, asked Dr. Daugan to modify GR30040x, which (along with other beta-carboline lead compounds) had been identified at Glaxo as a potent PDE5 inhibitor. *Id.* 62a. Dr. Daugan then worked independently to make structural modifications to the beta-carboline backbone (the "scaffold") of GR30040x.

Dr. Daugan conducted an extensive series of experiments as he sought, through "trial and error," to create a more potent, selective, and orally effective PDE5 inhibitor. Ct. App. J.A. 453:19-455:17. As part of that search, he made a series of analogs of GR30040x, creating "several hundred[]" compounds as he strove "to identify the best compound." *Id.* 674:12-20. For example, from June to December 1992, Dr. Daugan focused on compounds with a four-ring backbone comprising a three-ring beta-carboline structure linked to a five-membered "hydantoin" ring, but these proved ineffective when taken orally. *Id.* 693:23-700:3. Dr. Daugan then tried replacing the five-membered hydantoin ring found in the GR30040x analogs with a six-membered piperazinedione ring, a substitution that led to his discovery of a group of compounds that he later designated "Formula (I)" in the patents-in-suit. *Id.* 699:22-701:19, 2650, 7553-7562, 7517. Dr. Daugan continued studying and altering this new family of compounds, creating and testing scores of compounds with dispa-

rate chemical substituents, and by June 1993, he had invented tadalafil. *Id.* 662:6-664:4, 701:7-703:22.

Dr. Labaudinière explained his initial identification of GR30040x as a "lead" compound, testifying without contradiction that his attention was drawn to two other beta-carbolines, designated CCI23002 and GR35273, because scientific literature and a separate Glaxo project had described them as inhibiting PDE5. Ct. App. J.A. 470:7-471:4. Dr. Labaudinière searched Glaxo's chemical-compound database for compounds with similar substructures and discovered potential candidates for further research, including GR30040x. *Id.* 470:7-25, 967. This unchallenged account was confirmed by testimony from Dr. Daugan and two experts, as well as by minutes from Glaxo meetings and Glaxo France's contemporaneous 1992-1993 Annual Report. Pet. App. 65a-69a; Ct. App. J.A. 2639-2699.

Dr. Daugan and Glaxo first sought patent protection for tadalafil and the other claimed compounds in 1994, when Glaxo filed a U.K. patent application. A U.S. patent application was filed under the Patent Cooperation Treaty in 1995, issuing as the '006 patent in 1999. A second U.S. patent application directed specifically to the use of tadalafil to treat ED was filed in 1996 and issued as the '329 patent in 2000. The relevant patent claims are directed to particular chemical compounds, pharmaceutical compositions comprising those compounds, and methods for using those compounds. Pet. App. 34a-36a. The rights in these inventions had previously been assigned to ICOS. *Id.* 7a, 34a.

In 2002, ICOS obtained approval to market tadalafil as the active ingredient in Cialis®, a commercial ED drug. In 2007, ICOS was acquired by Eli Lilly & Company.

B. Proceedings in the District Court

On July 20, 2005, years after Dr. Daugan obtained his patents and well after Cialis® became a commercial success, Petitioner Vanderbilt University sued ICOS under 35 U.S.C. § 256, alleging that three of its professors—Dr. Jackie D. Corbin, Dr. Sharron H. Francis, and Dr. Sekhar R. Konjeti—should be added to the patents-in-suit as joint inventors with Dr. Daugan. Pet. App. 2a.

The district court held a bench trial on Vanderbilt's correction-of-inventorship claim. Vanderbilt did not contend that its professors had conceived tadalafil; the parties agreed that Dr. Daugan alone had done so. Pet. App. 23a. The Vanderbilt professors acknowledged that they had never had any contact with Dr. Daugan: Dr. Corbin admitted that he "never met Dr. Daugan," had no "direct connection with Dr. Daugan," had "never worked together with Dr. Daugan to solve any kind of a problem," and was "working independently" from Dr. Daugan. Ct. App. J.A. 386:4-387:5. Dr. Konjeti similarly admitted that he "didn't know that Dr. Daugan existed" and "never had any collaboration" with him. *Id.* 595:16-23. The record contains no evidence or suggestion that either the professors or Vanderbilt ever filed any application claiming inventorship of any compounds comprising a beta-carboline substructure, and certainly not tadalafil or any of the other compounds claimed in the '006 patent.

The evidence also showed that the Vanderbilt professors had no inkling that the beta-carboline compounds Dr. Daugan was studying could even be used as PDE5 inhibitors. Pet. App. 79a (citing Vanderbilt's written responses to ICOS's Requests for Admission). Dr. Corbin admitted that he "didn't know that anyone

in the world was working on beta-carboline compounds to make PDE-5 inhibitors" in 1992 or 1993, and he "didn't think of using beta-carboline compounds" at that time. Ct. App. J.A. 383:3-14. Dr. Konjeti similarly admitted that he "didn't know that beta-carboline compounds could inhibit PDE," was not aware of the structure of the compounds claimed in the patents, and "hadn't thought of any methods for making the ... compounds claimed in the patents." *Id.* 592:5-593:20, 594:16-595:2. Accordingly, Vanderbilt likewise filed no patent applications directed to the uses of such compounds claimed in the '329 patent.

Instead of allegations as to conception of the compounds and uses at issue, Vanderbilt rested its claim to joint inventorship on a highly attenuated "theory" or "hypothesis." Pet. App. 72a, 73a, 82a. Specifically, Vanderbilt ventured that a *non-beta-carboline* PDE5 inhibitor its professors identified—a compound known as 8-(4-hydroxy phenylthio)-isobutylmethylxanthine, designated an "IBMX analog"—led to Dr. Daugan's invention of the beta-carboline compounds claimed in the patents. *Id.* 36a. Vanderbilt's theory involved a complex chain of hypothetical events, none of which was supported by evidence. Indeed, Vanderbilt admitted that it had "no direct evidence to support its view of the facts," but took the position that it "'need not prove specifically how [its version of events] occurred, but simply how it logically could have occurred.'" Pet. App. 17a; *see also id.* 73a.

Vanderbilt's theory was that Dr. Daugan's discovery of tadalafil resulted from the Vanderbilt professors' recognition of potent PDE5 inhibition by the IBMX analog (which was *not* a beta-carboline). The professors had included their finding regarding the IBMX analog in a January 3, 1992 research funding proposal

sent to Dr. Barry Ross, a scientist at Glaxo U.K. Pet. App. 5a. On April 8, 1992, Dr. Ross forwarded the proposal to a group including Dr. Labaudinière. *Id.* 6a. At that point, Vanderbilt's theory departed the realm of evidence and rested entirely on speculation. Vanderbilt contended, without evidentiary support, that (1) Dr. Labaudinière immediately read the proposal; (2) he somehow recognized four unidentified "structural features" of Vanderbilt's IBMX analog that were purportedly central to its inhibition of PDE5; and (3) he used some of those "features" to inform the database search that led him to identify GR30040x, which he then directed Dr. Daugan to research. *Id.* 73a-75a. Alternatively, Vanderbilt argued (4) that Dr. Daugan himself learned of the Vanderbilt professors' disclosure of the IBMX analog, and (5) used some of that IBMX analog's features to guide his modification of GR30040x, which eventually led to his invention of the patented compounds. *Id.* 75a-76a.

As mentioned, Vanderbilt had *no* direct evidence for its speculative chain of events. Indeed, the features that it argued Dr. Labaudinière utilized and conveyed to Dr. Daugan—which it now refers to as "Vanderbilt Structural Features"—were not identified as being necessary or sufficient for improving the potency of any PDE5 inhibitor in any contemporaneous document, including the January 1992 proposal or any other internal Vanderbilt documents. Ct. App. J.A. 423:11-425:3, 756:5-12, 763:13-765:19, 843:14-847:3, 1831-1836. Indeed, prior to an expert report and testimony in this case (*id.* 418:6-24), Vanderbilt had never referred to these elements as a related set of features in any communication to Glaxo. Nor did Vanderbilt name these elements the "Vanderbilt Structural Features" until after the trial had finished—the first such mention appeared in Van-

derbilt's post-trial brief. Dkt. No. 149 at 22 (D. Del. Feb. 25, 2008).

ICOS countered Vanderbilt's speculation with extensive evidence, including contemporaneous documents and undisputed testimony from fact and expert witnesses, all of which showed that the Vanderbilt professors' research had no influence on either Dr. Labaudinière or Dr. Daugan. As for Vanderbilt's first theory, unrebutted testimony showed that Dr. Labaudinière (1) did not conduct his search for beta-carboline compounds based on the supposed "Vanderbilt Structural Features"; (2) would not have conducted such a search because it would have been scientifically unsound and impractical; and (3) would not have discovered GR30040x by performing the search as Vanderbilt conjectured. Ct. App. J.A. 438:21-439:12, 470:7-471:4, 942:16-24. Indeed, Dr. Labaudinière's unrebutted testimony showed that he did not know about Vanderbilt's research until June 1993—months after Dr. Daugan conceived the claimed compounds. *Id.* 438:21-439:12, 7369.

Regarding Vanderbilt's alternative theory that Dr. Daugan himself knew of and was influenced by the Vanderbilt professors' IBMX analog, Dr. Daugan provided direct and unchallenged testimony that, before the lawsuit, he had never (1) seen any document written by the Vanderbilt professors, (2) seen the results of any experiment they conducted, (3) discussed their work with anyone, (4) known anything about their research, or (5) been influenced by any theory based on the "structural features" of an IBMX analog. Ct. App. J.A. 668:17-669:4. Rather, Dr. Daugan explained that his effort was an independent, extensive empirical research study based on trial and error, explicitly stating that "no information and no one influenced [him] in the

design and conception of the [claimed] compounds." *Id.* 674:6-7; *see also id.* 658:17-659:3, 660:5-9, 660:22-661:21, 674:3-20, 677:13-684:6, 693:19-703:17. Finally, Dr. Daugan testified that, even if he had known that the IBMX analog was a potent PDE5 inhibitor, that would not have helped him design the claimed beta-carboline compounds, because the two different kinds of compounds had no relevant structural similarity. *Id.* 673:1-11; *see also id.* 7516-7542.

The district court ruled that Vanderbilt failed to prove that Drs. Corbin, Francis, or Konjeti were inventors of either the '006 or '329 patents. Pet. App. 31a-83a. The court articulated two reasons for rejecting Vanderbilt's correction-of-inventorship claim. *First*, the court ruled that there was "no evidence that [the Vanderbilt professors] ever conceived the 'specific chemical structure of the compound' claimed," a matter the court deemed dispositive under binding precedent. *Id.* 79a-80a n.50. *Second*, the court noted the "lack of evidence" supporting Vanderbilt's theory that Dr. Labaudinière communicated any of Vanderbilt's "structural features" to Dr. Daugan. *Id.* 79a n.50. As for how Dr. Labaudinière identified GR30040x, while the court criticized ICOS's position in some respects (*id.* 80a-81a), its ultimate conclusion was that both parties' accounts were "equally plausible with respect to the identification of GR30040x." *Id.* 82a.

C. Proceedings in the Court of Appeals

The Federal Circuit affirmed on the second basis articulated by the district court. As to the first basis, the court of appeals accepted Vanderbilt's argument that a co-inventor need not have "an independent mental picture of the complete compound claimed"; it sufficed that "a group of co-inventors must collaborate and

work together to collectively have a definite and permanent idea of the complete invention." Pet. App. 22a.

However, the court of appeals affirmed based on the district court's finding that the parties' accounts of the identification of the GR30040x compound—which, though not claimed in the patents, was the linchpin of Vanderbilt's theory of co-inventorship—were "'equally plausible'" and that "Vanderbilt failed to produce any evidence of joint invention of tadalafil." Pet. App. 23a. Accordingly, the court ruled that, "under the correct legal test, Vanderbilt did not carry its burden. Thus, any erroneous interpretations of our case law were harmless error." *Id.*; *see also id.* 19a ("These errors, however, do not affect the outcome of this appeal and are therefore harmless in context. When tested by the correct law, the facts of the case still require affirmance.").

Judge Dyk concurred in part and dissented in part. Judge Dyk agreed that the evidence supported the district court's ruling that Dr. Daugan "did not himself directly utilize the Vanderbilt scientists' contributions." Pet. App. 26a. Judge Dyk maintained, however, that the court "could not have properly found that the Vanderbilt scientists made a contribution to the identification of GR30040x if it were 'equally plausible' that they did not make a contribution." *Id.* 28a. Alternatively, Judge Dyk believed that the district court's opinion could be read as irretrievably "tainted" by its legal error that a joint inventor was required to conceive the entire claimed invention. *Id.* 28a-29a.

The Federal Circuit denied Vanderbilt's petition for rehearing and rehearing en banc. Pet. App. 86a-87a.

REASONS FOR DENYING THE PETITION

I. THE STANDARD OF PROOF IS NOT OUTCOME-DETERMINATIVE AND DOES NOT MERIT REVIEW

Vanderbilt's attempt to hitch its wagon to this Court's grant of certiorari in *i4i* depends on ignoring Vanderbilt's failure to convince either the district court or the court of appeals that its theory of events based on speculation was any more plausible than ICOS's account of the invention based on evidence. Even if this Court were to grant certiorari, receive merits briefs, hear oral argument, and reverse the Federal Circuit's application of a "clear and convincing" standard of proof, the outcome would be exactly the same: a judgment that Vanderbilt failed to carry its burden, because the district court found that Vanderbilt's theory was no more than "equally plausible" compared to ICOS's account. Pet. App. 82a. The Court is rightly disinclined to review cases in which reversal will not affect the actual controversy between the parties, and it should not make an exception here.

Additionally, the Federal Circuit's settled requirement that a putative co-inventor must adduce clear and convincing evidence of inventorship in order to prevail under 35 U.S.C. § 256 is correct. The statute simply codified preexisting common law on the matter, which Congress has never abrogated. Regardless of the outcome in *i4i*, there is no reason to reconsider the standard of proof in correction-of-inventorship cases—an issue on which the Court has previously denied certiorari.

A. This Case Is An Unsuitable Vehicle Because Reversal On The Question Presented Cannot Alter The Outcome

Although the clear-and-convincing-evidence standard was invoked below to reinforce Vanderbilt's failure to support its theory with evidence, the courts below could and—based on their express statements—would have reached the very same result under a preponderance standard. As the district court and the court of appeals majority recognized, Vanderbilt's theory was at most "equally plausible" when compared to the account ICOS supported with evidence. Pet. App. 23a, 82a. It is settled—and Vanderbilt does not dispute—that "when the evidence is evenly balanced, the [burdened party] must lose." *Director, Office of Workers' Compensation Programs* v. *Greenwich Collieries*, 512 U.S. 267, 281 (1994); *see also Gonzales* v. *O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 428 (2006) (government failed to carry its burden where the evidence was "in equipoise"); *Concrete Pipe & Prods. of Cal., Inc.* v. *Construction Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993) (preponderance-of-the-evidence standard requires "the trier of fact to believe that the existence of a fact is *more probable* than its nonexistence before [it] may find in favor of the party who has the burden" (emphasis added; internal quotation marks omitted)).[1]

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[1] Vanderbilt does not dispute the proposition that, even under a preponderance standard, it would still bear the burden of proof as the party seeking to change the status quo. *See, e.g.*, *Schaffer ex rel. Schaffer* v. *Weast*, 546 U.S. 49, 57-58 (2005) ("Absent some reason to believe that Congress intended otherwise, ... the burden of persuasion lies where it usually falls, upon the party seeking relief."); 1 Mueller & Kirkpatrick, *Federal Evidence* § 3.1, at 104

This Court generally does not grant certiorari to resolve legal issues that will not affect the outcome of the case in which they arise. *See, e.g.*, Gressman *et al.*, *Supreme Court Practice* § 4.4(f), at 248 (9th ed. 2007) (citing *Sommerville* v. *United States*, 376 U.S. 909 (1964)).[2] That practice is sound, as the fact that the decision below ultimately did not turn on the issue presented raises the question whether the issue is dispositive in *any* case, or at least arises sufficiently frequently to merit this Court's intervention.

Although Vanderbilt cites the number of amicus briefs supporting the petition in *i4i* (Supp. Br. 2), it is notable that *not one* amicus supported Vanderbilt's petition here, nor did any of the *i4i* briefs suggest that the Court should alter the longstanding requirement of clear and convincing evidence in correction-of-inventorship cases. Indeed, a Section 256 plaintiff must *corroborate* his or her own testimony with objective evidence—a common-law requirement of proof that Vanderbilt accepts as proper under the statute, while recognizing that it is "unique[]" to the correction-of-inventorship context. Pet. 20. Yet the independent corroboration requirement in correction-of-inventorship cases is closely linked to the requirement

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(3d ed. 2007) ("Perhaps the broadest and most accepted idea is that the person who seeks court action should justify the request, which means that the plaintiffs bear the burdens on the elements in their claims.").

[2] In *Sommerville*, the circuit panel was divided as to whether liability was governed by state or federal law, and the courts of appeals were similarly divided, but the disagreement was theoretical because the defendant would have been liable under either approach. *United States* v. *Sommerville*, 324 F.2d 712, 714, 717 n.16 (3d Cir. 1963); *see also id.* at 720 (Steel, J., concurring).

of clear and convincing evidence. *See, e.g.*, *The Barbed Wire Patent*, 143 U.S. 275, 284 (1892) (holding that testimony in patent cases is often "unsatisfactory" and requiring proof that is "clear, satisfactory, and beyond a reasonable doubt"); *Deering* v. *Winona Harvester Works*, 155 U.S. 286, 300, 301 (1894) ("grave suspicion" regarding testimony requires "evidence so cogent as to leave no reasonable doubt in the mind of the court that the transaction occurred substantially as stated"); *Trovan, Ltd.* v. *Sokymat SA*, 299 F.3d 1292, 1302 (Fed. Cir. 2002) ("To meet the clear and convincing burden of proof, alleged co-inventors must prove their contribution to the conception with more than their own testimony[.]"); *Price* v. *Symsek*, 988 F.2d 1187, 1194 (Fed. Cir. 1993) (claims to priority or derivation are "regarded with skepticism," so that "without some type of corroborating evidence, an alleged inventor's testimony cannot satisfy the 'clear and convincing evidence' standard"). Here, of course, Vanderbilt provided *no evidence*, let alone corroboration, of its theory that Dr. Daugan's invention of tadalafil was somehow influenced by the Vanderbilt professors' work with the IBMX analog.[3]

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[3] Vanderbilt states in a footnote that documentary evidence corroborated the Vanderbilt professors' discovery *of the IBMX analog*. Pet. 21 n.5. But the patents at issue do not claim the IBMX analog; rather, they claim *tadalafil* and other beta-carboline compounds. As the courts below held, *no* direct evidence corroborates Vanderbilt's speculation that its professors had *any* role whatsoever in Dr. Daugan's conception of the claimed beta-carboline compounds. Pet. App. 17a. Vanderbilt's failure to provide corroboration for its claims of co-inventorship provides an independent basis for affirmance, further counseling against a grant of review.

To be sure, the opinions below framed Vanderbilt's failure of proof in terms of a lack of "clear and convincing evidence" (Pet. App. 23a, 82a n.53), but that is understandable in light of the precedent that bound both courts. *E.g.*, *Hess* v. *Advanced Cardiovascular Sys., Inc.*, 106 F.3d 976, 979-980 (Fed. Cir. 1997). Nevertheless, the finding that the evidence regarding the identification of GR30040x was in equipoise would manifestly compel the same conclusion under a preponderance standard.

Vanderbilt has precious little to say about the effect of the finding that its theory was only "equally plausible" compared to ICOS's account (Pet. App. 82a)—other than to contend that the district court's finding was error, supposedly because the court failed to consider certain evidence (Pet. 10). But the court of appeals implicitly rejected that argument when it complimented the district court for its "thorough review of all of the evidence." *Id.* 18a; *see also id.* 23a (citing the district court's "careful review of the evidence"). Whether the district court did or did not consider particular evidence—and whether the court of appeals correctly found no error—is a case-specific factual determination that does not warrant this Court's review. *See* S. Ct. R. 10 (certiorari is "rarely granted" when the petition asserts "erroneous factual findings"); *United States* v. *Johnston*, 268 U.S. 220, 227 (1925) (Holmes, J.) ("We do not grant a certiorari to review evidence and discuss specific facts."). Certiorari is particularly unwarranted where, as here, "the findings of fact made by the district court receive the concurrence of the court of appeals." Gressman, § 4.14, at 271; *see also Berenyi* v. *District Dir., INS*, 385 U.S. 630, 635 (1967) (following the "Court's repeated pronouncements" against reviewing factual findings that were "reached by the Dis-

trict Judge and accepted by the Court of Appeals"); *Graver Tank & Mfg. Co.* v. *Linde Air Prods. Co.*, 336 U.S. 271, 275 (1949) ("A court of law, such as this Court is, rather than a court for correction of errors in fact finding, cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error.").

Vanderbilt also claims that the district court "found that Vanderbilt's scientists contributed *to the process* through which Dr. Daugan invented the compounds." Pet. 11 (emphasis added) (citing Pet. App. 80a). But a contribution to the "inventive process" (Pet. App. 80a) is not the same as a contribution to the conception of the invention itself. *See, e.g.*, *Ethicon, Inc.* v. *U.S. Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998) ("Because conception is the touchstone of inventorship, each joint inventor must generally contribute to the conception of the invention." (alteration and internal quotation marks omitted)). The district court accordingly cited a case that expressly distinguished between significant "contributions to conception" on the one hand and "prosaic contributions to *the inventive process* that do not render the contributor a co-inventor" on the other. *Eli Lilly & Co.* v. *Aradigm Corp.*, 376 F.3d 1352, 1359 (Fed. Cir. 2004) (emphasis added) (cited at Pet. App. 80a). The court specifically ruled that the Vanderbilt scientists' contributions to Dr. Daugan's "inventive process," if any, were of the second "'prosaic'" kind. Pet. App. 80a. Indeed, the parties agreed that Dr. Daugan, and Dr. Daugan alone, conceived tadalafil and the other claimed compounds. *Id.* 23a.

Moreover, as the court of appeals correctly ruled, the district court's ultimate finding, reviewing the evidence in full, was that even Vanderbilt's theory as to the identification of GR30040x—which was at most a

"prosaic" step in Dr. Daugan's "inventive process," not itself an inventive contribution—was itself no more than "equally plausible." Pet. App. 23a, 82a. The panel majority ruled that the principal finding that the parties' accounts were "equally plausible" compelled a finding that Vanderbilt failed to carry its burden—a determination that would stand under a preponderance test as well. Vanderbilt may well disagree with that view, but the interpretation of a particular trial court opinion in a particular case does not warrant this Court's intervention.

Vanderbilt has no other path to relief in this case. The panel was unanimous—and Vanderbilt does not seriously dispute—that there was *no* evidence (let alone a preponderance) that the Vanderbilt professors collaborated with Dr. Daugan himself, which would have required an "open line of communication during ... [the named inventor's] inventive efforts," *Cook Biotech Inc.* v. *ACell, Inc.*, 460 F.3d 1365, 1373 (Fed. Cir. 2006) (internal quotation marks omitted), as well as "some element of joint behavior." *Kimberly-Clark Corp.* v. *Procter & Gamble Distrib. Co.*, 973 F.2d 911, 917 (Fed. Cir. 1992) ("Individuals cannot be joint inventors if they are completely ignorant of what each other has done[.]"). As the court of appeals noted, there was no evidence of any collaboration here. Pet. App. 16a-19a; *see also id.* 26a (Dyk, J., concurring in part and dissenting in part) (agreeing with panel majority in upholding the district court's finding that Dr. Daugan "did not himself directly utilize" the Vanderbilt professors' work). And Vanderbilt does not dispute that disclosure to a company like Glaxo is insufficient to establish disclosure to an individual inventor. *See Beall* v. *Ormsby*, 154 F.2d 663, 665-666 (C.C.P.A. 1946).

Thus, Vanderbilt's only route to success was to prove (1) that Dr. Labaudinière searched for and found GR30040x based on his knowledge of Vanderbilt's IBMX analog and (2) that the identification of GR30040x was in fact an inventive (and not a "prosaic") contribution to the conception of tadalafil. But as the court of appeals found, Vanderbilt's case failed on the first point. There was "no clear error in the district court's factual findings underpinning its determination regarding Glaxo's identification of GR30040x" (Pet. App. 18a), given Vanderbilt's failure to offer anything more than attorney argument to support its claim in the face of "direct evidence supporting Dr. Labaudiniere's claim to sole identification of GR30040x" (*id.* 17a). Even viewing ICOS's evidence with skepticism, the district court found that Vanderbilt's case did not surpass "equal[]" plausibility. *Id.* 82a. And on the key question whether the Vanderbilt scientists "communicated to Glaxo a compound of the general structure of [the compounds] of the patents at issue," Vanderbilt's presentation was "devoid of evidence." *Id.* 79a. Thus, Vanderbilt's claim was properly rejected no matter what standard of proof applied.

As is discussed in the following section, the Court should not reassess the settled standard of proof applicable in correction-of-inventorship cases under Section 256. But even if the Court were interested in embarking on such a venture, this case is not a suitable vehicle for it. Merits review in this case would be a moot court that would unnecessarily squander Court and party resources. If the issue is as important as Vanderbilt in-

sists it is, the Court can await a case in which it might actually make a difference.[4]

B. Even If This Case Were A Suitable Vehicle, The Clear-And-Convincing-Evidence Standard For Correction-Of-Inventorship Claims Would Not Merit Review

Even if Vanderbilt's Section 256 claim could succeed under a preponderance standard—and it cannot—the Federal Circuit's decades-long jurisprudence that such claims require clear and convincing evidence is correct and should not be upset. The Court should therefore decline to review the issue, just as it has before. Pet. for Cert. 12, *D.S. Brown Co.* v. *Acme Highway Prods. Corp.*, No. 70-1140 (U.S. Dec. 21, 1970) (contending that the court of appeals "erred ... in its ruling that joint inventorship must be proven by clear and convincing evidence"), *cert. denied*, 401 U.S. 956 (1971).

Vanderbilt's primary argument for certiorari in this case is that claims under Section 256 are exactly the same as all other civil claims. Pet. 21. But Section 256 was not enacted in a vacuum. Rather, it was part of

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[4] Vanderbilt is wrong to suggest (Pet. 22-23) that an error regarding the standard of proof can never be harmless. *See, e.g.*, *Bowoto* v. *Chevron Corp.*, 621 F.3d 1116, 1124 (9th Cir. 2010) (affirming where "any difference in the burden of proof" would be "immaterial under the circumstances of this case"). Indeed, courts of appeals have affirmed even where the district court has placed the burden on the wrong *party*. *E.g.*, *Barth* v. *Gelb*, 2 F.3d 1180, 1189 (D.C. Cir. 1993) ("Viewing the evidence through the lens of those findings, we conclude that it was not so closely balanced that the court's error in assigning the burden of persuasion to Mr. Barth would have affected the outcome."); *Cates* v. *Morgan Portable Bldg. Corp.*, 780 F.2d 683, 688 (7th Cir. 1985) ("The judge's error about who had the burden of proof was harmless.").

the 1952 Patent Act, which—among other things—codified several preexisting patent law doctrines. *E.g.*, Lutz, *The New 1952 Patent Statute*, 35 J. Pat. Off. Soc'y 155, 156 (1953) ("Congress ... codified some doctrines of patent law that were developed in the courts by 'common law' processes."). The requirement of clear and convincing evidence predated the 1952 Act by at least three years. *See Pointer* v. *Six Wheel Corp.*, 177 F.2d 153, 157 (9th Cir. 1949) ("[I]t must appear by clear and convincing proof that the two inventors collaborated in evolving the patented device."). Congress is presumed to legislate on the background of that doctrine—a principle Vanderbilt does not appear to contest with respect to the requirement of independent corroboration of inventorship evidence. Pet. 20-21; *see Abuelhawa* v. *United States*, 129 S. Ct. 2102, 2106 (2009) ("legislatures act with case law in mind," so that Congress is presumed to be familiar with "traditional judicial" approaches); *Beck* v. *Prupis*, 529 U.S. 494, 501 (2000) (Congress "presumably knows and adopts the cluster of ideas that were attached" to statutory terms, so that the "absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them" (internal quotation marks omitted)); *North Star Steel Co.* v. *Thomas*, 515 U.S. 29, 34 (1995) ("'[I]t is not only appropriate but also realistic to presume that Congress was thoroughly familiar with [our] precedents ... and that it expect[s] its enactments to be interpreted in conformity with them.'" (quoting *Cannon* v. *University of Chi.*, 441 U.S. 677, 699 (1979)).[5]

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[5] *Accord, e.g.*, *Merck & Co.* v. *Reynolds*, 130 S. Ct. 1784, 1795 (2010) (citing cases); *Miles* v. *Apex Marine Corp.*, 498 U.S. 19, 32

Decisions in several circuits have articulated the clear-and-convincing standard under the 1952 Act,[6] yet Congress has never sought to alter that settled requirement, despite remaining "'free to alter what [courts] have done.'" *Watson* v. *United States*, 552 U.S. 74, 82 (2007). In 1984, Congress amended the definition of a joint inventor in Section 116, expressly referencing lower court decisions. Pet. App. 10a (noting that the 1984 amendments codified the principles of *Monsanto Co.* v. *Kamp*, 269 F. Supp. 818 (D.D.C. 1967)). Those amendments made it easier to become a joint inventor, by recognizing for example joint inventors who did not physically work together, but Congress elected not to relax the uniformly-applied standard of proof in correction-of-inventorship cases. "The responsibility for changing [settled law] rests with Congress," *Festo Corp.* v. *Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535

(1990) (Congress "must have intended to incorporate" the established judicial "gloss" because "Congress is aware of existing law when it passes legislation"); *Goodyear Atomic Corp.* v. *Miller*, 486 U.S. 174, 184-185 (1988) ("We generally presume that Congress is knowledgeable about existing law pertinent to the legislation it enacts."); *T.I.M.E. Inc.* v. *United States*, 359 U.S. 464, 474 (1959) (Supreme Court "cannot assume [Congress] was unaware" of a common law decision relevant to its establishment of a statutory scheme).

[6] *E.g.*, *Hess*, 106 F.3d at 980; *Acme Highway Prods. Corp.* v. *D.S. Brown Co.*, 431 F.2d 1074, 1083 (6th Cir. 1970) ("[I]t has been well established that joint inventorship must be proven by clear and convincing evidence."); *Garrett Corp.* v. *United States*, 422 F.2d 874, 880 (Ct. Cl. 1970) ("The burden of showing misjoinder or nonjoinder of inventors is a heavy one and must be proved by clear and convincing evidence"); *see also Levin* v. *Septodont Inc.*, 34 F. App'x 65, 70 (4th Cir. 2002) (party seeking to correct patent's list of inventors "must prove that claim by clear and convincing evidence").

U.S. 722, 739 (2002), and Congress has declined to make the change that Vanderbilt seeks.[7]

In its supplemental brief, Vanderbilt belatedly attempts to liken its case to *i4i*, which involves the applicability of a clear-and-convincing-evidence standard in invalidity challenges based on prior art not placed before the Patent Office. *See* Pet. for Cert. i, *Microsoft Corp.* v. *i4i Ltd. P'ship*, No. 10-290 (U.S. Aug. 27, 2010). But as Vanderbilt recognizes, eleven amicus briefs supported Microsoft's petition for certiorari, emphasizing the claimed frequency with which the standard of proof may be dispositive in invalidity cases. By contrast, not one amicus has supported Vanderbilt's petition in this case or even suggested that it raises a question of significant importance. As shown in the preceding section, even *this case* does not turn on the issue.[8]

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[7] Clear and convincing evidence is additionally appropriate because claims under 35 U.S.C. § 256 are equitable in nature, *Shum* v. *Intel Corp.*, 499 F.3d 1272, 1277 (Fed. Cir. 2007), and plaintiffs seeking equitable relief have historically had to prove factual contentions by clear and convincing evidence. *See* 2 *McCormick on Evidence* § 340 & n.15, at 488 (6th ed. 2006) (citing cases). In fact, one authoritative commentator has questioned whether Section 256 creates an independent cause of action at all, given that the statutory language does not purport to do so. *See* 1 *Chisum on Patents* § 2.04[7], at 2-142 (Nov. 2007) (finding the existence of federal jurisdiction under Section 256 "highly questionable, both in terms of the statutory language of Section 256 and of policy").

[8] Although the use of a clear-and-convincing standard to prove co-inventorship has been linked to the presumption of validity, *see, e.g.*, *Stern* v. *Trustees of Columbia Univ. in City of N.Y.*, 434 F.3d 1375, 1377 (Fed. Cir. 2006), the standard is supported by other "important policy considerations"—most notably countering the temptation for aspiring co-inventors to reconstruct their prior

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No matter how *4i* is resolved, the outcome in this case will be the same, because Vanderbilt failed to prove that its professors are entitled to be named co-inventors by even a preponderance, and clear and convincing evidence is a longstanding common law standard that Congress has implicitly approved and never disturbed. There is no need, and certainly no pressing need, for this Court to review Vanderbilt's first question presented.

II. An Appellate Court's Authority To Affirm On An Alternative Ground Supported By The Record Is Settled, Particularly Where The District Court Has Made The Necessary Supporting Findings

Vanderbilt's second question presented is almost an afterthought, and understandably so: it attempts to discard a settled doctrine that this Court and every circuit have articulated countless times, namely that an appellate court "may affirm on any ground that the law and the record permit." *Thigpen* v. *Roberts*, 468 U.S. 27, 30 (1984); *see also, e.g.*, *Jaffke* v. *Dunham*, 352 U.S. 280, 281 (1957) (per curiam) ("A successful party in the

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state of mind and inflate their contributions, "particularly where, as here, the patent has been outstanding for a considerable time and the patented device has been successful." *Hess*, 106 F.3d at 980 (citing *Amax Fly Ash Corp.* v. *United States*, 514 F.2d 1041, 1047 (Ct. Cl. 1975)). These considerations have particular force in this case, where scientists came forward years after the patents issued to assert—without evidence—joint inventorship of a highly successful commercial product.

District Court may sustain its judgment on any ground that finds support in the record.").[9]

Here, the Federal Circuit's affirmance was all the more justified because it rested on a basis that *the district court itself accepted.* As the panel majority explained, the district court "did not rest its opinion solely" on the interpretation of the law of inventorship that the Federal Circuit held erroneous. Pet. App. 23a. Rather, the district court—like the Federal Circuit—*separately* ruled that Vanderbilt failed to carry its burden to show that its professors contributed to the conception of the claimed compounds, because its speculative theory of events regarding the identification of the unclaimed GR30040x compound was only "equally plausible" when compared to ICOS's evidence. *Id.* 23a, 82a. That finding sufficed to support the judgment, and the Federal Circuit was fully entitled to affirm on that basis notwithstanding disagreeing with the district court's alternative ground of decision. *See, e.g.*, *Morgan Stanley Capital Group Inc.* v. *Public Util. Dist. No. 1 of Snohomish County*, 128 S. Ct. 2733, 2749 (2008) (affirming "on alternative grounds," despite "significant disagreement" with the lower court); *Siegert* v. *Gilley*,

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[9] *Accord Carreras* v. *Sajo, Garcia & Partners*, 596 F.3d 25, 36 (1st Cir. 2010); *Shelton* v. *Kennedy Funding, Inc.*, 622 F.3d 943, 952 (8th Cir. 2010); *Friends of Tims Ford* v. *TVA*, 585 F.3d 955, 964 n.2 (6th Cir. 2009); *Brooks* v. *Ross*, 578 F.3d 574, 578 (7th Cir. 2009); *Berquist* v. *Washington Mut. Bank*, 500 F.3d 344, 349 (5th Cir. 2007); *United States* v. *Smith*, 395 F.2d 516, 519 (4th Cir. 2005); *Davis* v. *Roberts*, 425 F.3d 830, 834 (10th Cir. 2005); *Green* v. *CSX Transp., Inc.*, 414 F.3d 758, 765 (7th Cir. 2005); *Koziara* v. *City of Casselberry*, 392 F.3d 1302, 1306 n.2 (11th Cir. 2004); *ACEquip Ltd.* v. *American Eng'g Corp.*, 315 F.3d 151, 155 (2d Cir. 2003); *Serrano* v. *Francis*, 345 F.3d 1071, 1076-1077 (9th Cir. 2003); *Tourscher* v. *McCullough*, 184 F.3d 236, 240 (3d Cir. 1999).

500 U.S. 226, 234-235 (1991) (affirming even though the court of appeals misread precedent, because "[b]y a different line of reasoning, we reach the same conclusion").

The alternative ground of decision, which is supported by the evidence and findings of record, amply distinguishes this case from *Pullman-Standard* v. *Swint*, 456 U.S. 273 (1982). As Vanderbilt acknowledges, the district court in *Pullman-Standard* had *failed* to make findings on a matter that the Fifth Circuit held was legally relevant (a union's intent in an employment discrimination suit). Rather than remand to allow the district court "to make the missing findings," the Fifth Circuit made those findings itself, set aside the district court's factual finding of no discriminatory intent, and *reversed* the district court's decision. *Id.* at 275, 282-284, 291. This Court disapproved that practice because Federal Rule of Civil Procedure 52(a) "requires that findings of fact not be set aside unless clearly erroneous." *Id.* at 287; *see also id.* at 293. While a remand is indeed preferable where, as in *Pullman-Swint* and the other cases Vanderbilt cites, the court of appeals' reversal on a legal issue implicates factual matters on which no finding was made,[10] those rulings do

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[10] *See Impax Labs., Inc.* v. *Aventis Pharms. Inc.*, 468 F.3d 1366, 1383 (Fed. Cir. 2006) (remanding for a determination that had "not yet been done," because "the district court stopped its analysis"); *Trovan*, 299 F.3d at 1310 (remanding because the district court "did not completely address" claim construction issues); *W.L. Gore & Assocs., Inc.* v. *Garlock, Inc.*, 721 F.2d 1540, 1547 (Fed. Cir. 1983) ("the invention set forth in each claim was not in each instance considered as a whole," and "the references were not assessed in their entireties"); *see also United States* v. *Hasan*, 609 F.3d 1121, 1129 (10th Cir. 2010) (remanding where district court

not speak to this case, where the court of appeals affirmed on an alternative ground that remains unaffected by the legal ruling.

Here, the Federal Circuit did not make any new findings, set aside findings made by the district court, or reverse the district court's judgment. Rather, it *affirmed* on a ground that the trial court itself articulated and supported with its finding that Vanderbilt failed to carry its burden of proof (even by a preponderance). Thus, this is not a case in which the court of appeals "attempt[ed] to reach its own factual findings" or "usurp[ed] ... a trial court's role in weighing evidence against the appropriate legal standard." Pet. 25. Rather, the district court's finding of evidentiary equipoise was independent of its approach to inventorship law, and the panel majority *affirmed* that finding as based on "a careful review of the evidence." Pet. App. 23a. That finding compelled affirmance, even under Vanderbilt's desired standard of proof.[11]

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failed to undertake the first step in a "two-step, sequential inquiry").

Notably, three of the four cases Vanderbilt cites as applying the correct rule are from the Federal Circuit, which suggests either that Vanderbilt's supposed conflict does not exist or that it may be resolved by further percolation within the Federal Circuit.

[11] Since Vanderbilt's second question is presented independently of its first, it is properly considered on the basis that the Federal Circuit and district court correctly applied the clear-and-convincing-evidence standard. But even if a preponderance standard applied, the district court's findings still compel the same result. *See supra* Part I.A.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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